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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,020	09/21/2001	Christopher McDowell	COD-133	7026

27777 7590 12/28/2006  
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EXAMINER
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PICKETT, JOHN G

ART UNIT	PAPER NUMBER
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3728

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	12/28/2006	PAPER

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/960,020  
Filing Date: September 21, 2001  
Appellant(s): MCDOWELL, CHRISTOPHER

MAILED  
DEC 28 2006  
Group 3700

Eugene L. Szczecina, Jr.  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3 October 2006 appealing from the Office action mailed 12 September 2005.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

US 5,968,044	Nicholson et al.	10-1999
US 6,098,802	Asa et al.	08-2000
US 5,873,462	Nguyen et al.	02-1999

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3, 6, 8, 9, 11, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholson et al (US 5,968,044) in view of Asa et al (US 6,098,802) and Nguyen et al (US 5,873,462).

Regarding claim 1, Nicholson et al discloses a surgical fastener (**10, 34, and 70**) in the form of a disposable portion (**100**, see Col. 16, lines 2-10). Nicholson et al suggests placement of the surgical fasteners in a sterile tray (see for example, Col. 3, lines 37-38) but does not disclose the structure of said tray.

Both Asa et al and Nguyen et al disclose trays for the sterile storage of disposable portions (see for example, Asa Col. 1 line 17, and Nguyen Col. 2, lines 54-56).

Asa et al discloses a tray **10** with a base **12**, a plurality of wells **18**, a plurality of articles **P** disposed in the wells **18**, and a film **30**. Asa et al teaches the isolated wells to prevent cross-contamination.

Nguyen et al discloses tray **10** with a base **30**, a plurality of wells **31**, a plurality of articles **100** disposed in the wells **31**, and a film **150**. Nguyen et al anticipates scoring of the film **150** to allow for the controlled breaking of the film (see for example, Col. 3, lines 57-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the disposable surgical fastener assemblies of Nicholson et al in a tray as taught by either Asa et al or Nguyen et al in order to provide for independent dispensing of the fasteners.

The assembly of Nicholson-Nguyen discloses the claimed invention.

The assembly of Nicholson-Asa discloses the claimed invention except for the weakness in the film. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the film of Nicholson-Asa with scoring as taught by Nguyen et al in order to control the breakage of the film.

As to claim 3, the assemblies of Nicholson-Asa-Nguyen and Nicholson-Nguyen disclose scoring (see Nguyen, Col. 3, lines 57-63).

As to claim 6, the assemblies of Nicholson-Asa-Nguyen and Nicholson-Nguyen disclose scoring (see Nguyen, Col. 3, lines 57-63) as an ingress means.

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Regarding claims 8 and 9, both of the assemblies of Nicholson-Asa-Nguyen and Nicholson-Nguyen, as applied to claim 1, disclose the provision of the tray, the provision of the fastener, the covering of the well, and the modification of the film by presentation.

As to the sterilization, both Asa et al and Nguyen et al disclose sterilization (see for example, Asa, Col. 5 line 65 to Col. 6, line 7, and Nguyen Col. 3, lines 46-50) and it would have been obvious to one of ordinary skill in the art at the time the invention was made to include this feature for the assemblies either of Nicholson-Asa-Nguyen or Nicholson-Nguyen since the fasteners of Nicholson-Asa-Nguyen and Nicholson-Nguyen are to be used in a surgical procedure.

As to the penetration of the film, both Asa et al and Nguyen et al disclose accessing the articles by penetration of the film with an instrument (see Asa Figure 6, and Nguyen, Col. 3, lines 57-67).

As to claims 11 and 12, the assemblies of Nicholson-Asa-Nguyen and Nicholson-Nguyen disclose scoring (see Nguyen, Col. 3, lines 57-63).

As to claim 16, both Asa et al and Nguyen et al disclose accessing the articles by penetration of the film with an instrument (see Asa Figure 6, and Nguyen, Col. 3, lines 57-67). Both Asa et al and Nguyen et al form assemblies with the articles and instruments, which are necessary for their intended use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to penetrate the film of the assemblies of Nicholson-Asa-Nguyen or Nicholson-Nguyen with the applier (Nicholson 120) as taught by both Asa et al and Nguyen et al in order to form an assembly for the application of the fastener.

### **(10) Response to Argument**

Appellant asserts that Nicholson makes no mention whatsoever of the tray holding the bone fasteners and therefore there is no need to provide a plurality of wells or a weakened film. This argument is believed to be without merit. At column 3, lines 25-30, Nicholson describes the kit as including an expandable member and insertion element. At column 4, lines 62-65, Nicholson defines a bone fastener as including an insertion element and expandable member. At column 3, lines 37-38, Nicholson suggests the kit encased in a sterile tray. It is clear that Nicholson intends for the fasteners to be provided within the tray.

At column 16, lines 2-10, Nicholson discloses a disposable cartridge that is best viewed in Figure 23. The cartridge is identified as item **100**; the expandable member is identified as item **10**; the insertion element is identified as item **34**; and the holding means is identified as item **70**. As previously noted, Nicholson defines the bone fastener as including an insertion element and expandable member. As viewed in Figure 23, the disposable cartridge **100** is applied to an instrument **120** for application of the fastener (see for example column 16, lines 40-42). The entire assembly is defined as a kit and Nicholson suggests the kit be placed in a sterile tray. Appellant's assertion that they find no language in Nicholson that suggests the fastener within the tray is contrary to the direct recitations of the reference as cited above.

Further, Appellant uses open claim language. The fact that Nicholson discloses additional items within the tray that are not claimed by the appellant is irrelevant.

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Appellant's entire argument is based on the presumption that Nicholson does not suggest the kit or cartridge holding the fastener and therefore there is no need for the provision of the remaining claimed subject matter. As noted above, Nicholson defines a bone fastener as including an insertion element and expandable member (see column 4, lines 62-65). Nicholson describes the kit as including an expandable member and insertion element. Nicholson suggests the kit encased in a sterile tray. It is clear that Nicholson intends for the fasteners to be provided within the tray.

For these reasons, it is believed that the rejections should be sustained.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



J. Gregory Pickett  
Examiner

Conferees:



Mickey Yu  
SPE



Luan Bui  
Primary Examiner